Date of Approval: April 20, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-481

ALTRESYN Solution 0.22% (altrenogest)

Oral Solution

Horses

For suppression of estrus in mares

Sponsored by:

Ceva Sante Animale

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I. GENERAL INFORMATION:

A. File Number:	ANADA 200-481
B. Sponsor:	Ceva Sante Animale 10 Avenue de la Ballastiere 33500 Libourne France Drug Labeler Code: 013744 U.S. Agent: Mr. Douglas Rupp Ceva Animal Health 8906 Rosehill Road Lenexa, KS 66215
C. Proprietary Name:	ALTRESYN Solution 0.22%
D. Established Name:	Altrenogest
E. Pharmacological Category:	PROGESTIN
F. Dosage Form:	Solution
G. Amount of Active Ingredient:	Each mL of ALTRENOGEST Solution 0.22% contains 2.2 mg of altrenogest
H. How Supplied:	1000 mL plastic bottles
I. How Dispensed:	Rx
J. Dosage:	1 mL per 110 lbs body weight (0.044 mg/kg) once daily for 15 days
K. Route of Administration:	Oral
L. Species:	Horses
M. Indication:	ALTRESYN (altrenogest) Solution 0.22% is indicated to suppress estrus in mares. Suppression of estrus allows for a predictable occurrence of estrus following drug withdrawal. This facilitates the attainment of regular cyclicity during the transition from winter anestrus to the physiological breeding season. Suppression of estrus will also facilitate management of prolonged estrus conditions. Suppression of estrus may be used to facilitate scheduled breeding during the physiological breeding season.

N. Reference listed new animal drug:	REGU-MATE Solution 0.22%; altrenogest; NADA 131-310; Intervet, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Ceva Sante Animale, was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product ALTRESYN (altrenogest) Solution 0.22%. The generic product is administered as an oral solution with the same active ingredient in the same concentration and dosage form as the RLNAD. Further, this generic altrenogest solution does not contain any excipient or other change in formulation from the RLNAD that may significantly affect the absorption of the active ingredient. The RLNAD, REGU-MATE, was approved on September 7, 1983.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in horses, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to ALTRESYN Solution 0.22%:

Warning:

For oral use in horses only. Keep this and all other medication out of the reach of children. Do not use in horses intended for human consumption.

Skin contact must be avoided as Altresyn (altrenogest) Solution 0.22% is readily absorbed through unbroken skin. Protective gloves must be worn by all persons handling this product. Pregnant women or women who suspect they are pregnant should not handle Altresyn. Women of childbearing age should exercise extreme caution when handling this product. Accidental absorption could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

Information for Handlers:

Warning: ALTRESYN (altrenogest) Solution 0.22% is readily absorbed by the skin. Skin contact must be avoided; protective gloves must be worn when handling the product.

Effects of Overexposure: There has been no human use of this specific product. The information contained in this section is extrapolated from data available on other products of the same pharmacological class that have been used in humans. Effects anticipated are due to the progestational activity of altrenogest.

Acute effects after a single exposure are possible; however, continued daily exposure has the potential for more untoward effects such as disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy and headaches. The oil base may also cause complications if swallowed.

In addition, the list of people who should not handle this product (see at top of next column) is based upon the known effects of progestins used in humans on a chronic basis.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that ALTRESYN Solution 0.22%, when used according to the label, is safe and effective.